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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,333	09/24/2001	Vincent P. Stanton JR.	11926-015002	9730

26161 7590 12/09/2002

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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 12/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/963,333

Applicant(s)
Stanton

Examiner
Arun Chakrabarti

Art Unit
1634



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 5, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-49 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27, 38, and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 17-26, 28-37, and 39-48 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☒ Other: Detailed Action

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DETAILED ACTION

Election/Restriction

1. Applicant's election, without traverse, of claims 27, 38, and 49 corresponding to Group II in Paper No. 8 and species election in Paper numbers 8, 10, and 13, with traverse, are acknowledged. The traversal is on the ground(s) that the species belonging to the various polymorphisms in claims 27, 38, and 49 are all in the human thymidylate synthase gene and all represent either human TS cDNA or genomic sequences and none of these single nucleotide polymorphisms cause a change in the amino acid sequence of the human TS protein. This is found persuasive and therefore all the species are hereby examined although the group election has been made final.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application (60/093,484) and the divisional application 09/658,659 upon which priority is claimed fail to provide adequate support under 35 U.S.C. 112 for claims 27, 38, and 49 of this application. The provisional application (60/093,484) and the divisional application 09/658,659 does not disclose any basis of the single nucleotide polymorphisms of instant claims 27, 38, and 49. Applicant is hereby granted priority only to its filing date September 24, 2001.

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Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 27, 38, and 49 are rejected under 35 U.S.C. 103 (a) over Billing- Medel et al. (U.S. Patent 6,130, 043) (October 10, 2000) in view of Dean (U.S. Patent 6,087,489) (July 11, 2000).

Billing- Medel et al. teaches a method comprising :

(a) providing a sample comprising nucleic acid molecules present in a biological sample obtained from a patient (Abstract));

(b) contacting the sample with a probe comprising at least 15 contiguous nucleotides of the nucleotide sequence;

and

c) determining if the sample comprises a nucleic acid molecule that hybridizes to the probe.

Billing- Medel et al does not teach a probe comprising at least 15 contiguous nucleotides of the nucleotide sequence of SEQ ID NO: 6, the probe comprising at least one of :

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(I) nucleotide 1066 wherein N is C

(ii) nucleotide 1136 wherein N is G;

(iii) nucleotide 1497 wherein N is A; or the complements thereof (Abstract and SEQ ID NO: 1, Column 29, at position 1497 wherein N is the complement of A i.e., T),

or nucleotide 452 wherein N is A in SEQ ID NO: 7 (Abstract and SEQ ID NO: 1, Column 29, line 1),

or nucleotide 732 wherein N is C in SEQ ID NO: 8 (Abstract and SEQ ID NO: 1, Column 29, line 6).

Dean teaches a probe comprising at least 15 contiguous nucleotides of the nucleotide sequence of SEQ ID NO: 6, the probe comprising at least one of :

(I) nucleotide 1066 wherein N is C

(ii) nucleotide 1136 wherein N is G;

(iii) nucleotide 1497 wherein N is A; or the complements thereof (Abstract and SEQ ID NO: 1, Column 29, at position 1497 wherein N is the complement of A i.e., T),

or nucleotide 452 wherein N is A in SEQ ID NO: 7 (Abstract and SEQ ID NO: 1, Column 29, line 1),

or nucleotide 732 wherein N is C in SEQ ID NO: 8 (Abstract and SEQ ID NO: 1, Column 29, line 6).

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It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the probes comprising at least 15 contiguous nucleotides of the nucleotide sequence of SEQ ID NO: 6, the probe comprising at least one of :

(I) nucleotide 1066 wherein N is C

(ii) nucleotide 1136 wherein N is G;

(iii) nucleotide 1497 wherein N is A; or the complements thereof,

or nucleotide 452 wherein N is A in SEQ ID NO: 7,

or nucleotide 732 wherein N is C in SEQ ID NO: 8, of Dean into the method of identifying a nucleic acid molecule which is the diagnostic marker of a disease of Billing- Medel et al, since Dean states, "Methods of using these oligonucleotides for modulation of thymidylate synthase expression and treatment of diseases such as cancers believed to be responsive to modulation of thymidylate synthase expression are provided (Abstract, last sentence)." Dean further provides motivation as Dean states, "these methods can be used diagnostically or therapeutically (Column 1, lines 11-12)". By employing scientific reasoning, an ordinary practitioner would have been motivated to substitute and combine the diagnostic probes of Dean et al. into the method of identifying nucleic acid molecules which are diagnostic markers of Billing- Medel et al., in order to improve the method of identifying nucleic acids and also in order to achieve the express advantages, as noted by Dean et al., of an invention that provides diagnostic as well as therapeutic methods of using these oligonucleotides for modulation of

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thymidylate synthase expression and treatment of diseases such as cancers believed to be responsive to modulation of thymidylate synthase expression.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

December 2, 2002


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600